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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,618

03/10/2004

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EXAMINER

HALL, DEANNA K

ART UNIT

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3767

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/798,618	Applicant(s) WULFMAN ET AL.	
	Examiner DEANNA K. HALL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-13, 16-17, 19-21, 23-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-13, 16-17, 19-21, 23-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>September 2, 2005; March 7, 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on September 2, 2005 and March 7, 2007 are in compliance with the provisions of 37 CFR 1.97(b). Accordingly, the IDSs are being considered by the Examiner.

Double Patenting

2. Claims 1-5, 8-13, 16-17, 19-21 and 23-28 of this application conflict with claims 1-5, 8-13, 16-17, 19-21 and 23-28 of Application No. 10/798,621. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2, 4-5, 9-10, 12-13, 16-17, 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belef et al. (US 6,398,755) (“Belef”) in view of Ross et al. (US 6,258,111) (“Ross”). Belef discloses a catheter assembly comprising:

(claim 1) An operating head 56 coupled to a drive shaft and a drive assembly 4 for rotation C3 L15-21; a sealed lumen 36 mounted for axial translation at a proximal end with a control pod 22 and communicating at a distal end with the operating head; a control pod housing operational components for advancing the catheter system and selectably rotating the operating head C4 L54-C5 L9; and a console unit 6 incorporating system control and display features. (claim 5) The control pod incorporates selectable operator adjustment features allowing an operator to increase and decrease rotational speed delivered to the drive shaft 40. (claim 12) The control pod 22 incorporates a fluid seal assembly to prevent ingress of gas to the catheter system C6 L60-61. (claim 13) The control pod incorporates a speed adjustment selection switch controlling rotational speed transmitted to the drive shaft 40. (claim 16) The operating head, catheter system and control pod are provided as a sterile, disposable kit C3 L4. (claim 23) Belef further discloses an extendable telescoping guidewire support 51 mounted 26 in the control pod, Fig. 1. (claim 27) The console unit 6 is in electrical communication 8 with the control pod and provides power to the drive system. (claim 28) The console unit displays output operational information 10, C4 L43-46.

Belef discloses the invention as substantially claimed (see above) but does not directly show ports communicating with the sealed lumen or a motor providing vacuum for aspiration to the catheter assembly. (claim 1) Ross, in the analogous art, teaches

ports communicating with a sealed lumen, Fig. 19. (claim 24, 30) Ross also teaches a motor providing vacuum for aspiration to the catheter assembly C2 L28-43. The motor is controlled by a controller that is coupled to a foot pedal, see abstract. (claim 9-10, 25-26) The aspiration system comprising a plurality of vacuum pumps or a multi-lobed vacuum pump, Fig. 13. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Belef with the ports and the aspiration system as taught by Ross for removing debris from a vessel lumen. (claim 17) Further, it would be obvious to one skilled in the art to have a fluid receptacle in fluid communication with the catheter system to catch the aspirated liquid.

(claim 2, 4) It is the examiner's position that a drive motor that delivers a constant voltage or a drive motor that employs a cascaded variable regulator voltage source is well known in the art. The motor 54 of Belef could be either of these types of motors. (claim 29) It is also inherent that the console unit is a reuseable component.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Belef in view of Ross further in view of Fine et al. (5,358,509) ("Fine").

The combination of Befef/Ross teaches the invention as substantially claimed (see above). However, this combination does not directly disclose adjusting the rotational speed based on the load requirements by altering the current and voltage of the motor. Fine, in the analogous art, teaches adjusting the rotational speed based on the load requirements by altering the current and voltage of the motor C16 L36-45.

Therefore, it would have been obvious to a person having ordinary skill in the art at the

time the invention was made to have modified the device of Belef/Ross with the current and voltage adjustment as taught by Fine for providing a system with a drive motor that is adjusted dynamically to load conditions.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Belef in view of Ross further in view of Valley et al. (5,795,325) ("Valley").

The combination of Befef/Ross teaches the invention as substantially claimed (see above). However, this combination does not directly disclose a coil to reinforce and prevent the catheter from kinking. Valley, in the analogous art, teaches a tube may be reinforced with wire or filament braiding or coils for increased stiffness, torque control or kink resistance C22 L50-53. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Belef/Ross with the coil as taught by Valley for provide a sealed catheter that is kink-free.

7. Claims 11 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belef in view of Ross further in view of Nash et al. (US 6,080,170) ("Nash").

The combination of Befef/Ross teaches the invention as substantially claimed (see above). However, this combination does not directly disclose a coupling means between the drive shaft and drive motor comprising ball bearings and sliding tubes. Nash, in the analogous art, teaches a drive assembly comprising a drive shaft connected to a drive motor through a ball bearing assembly. Where the ball bearing assembly 350 comprising an outer tubes with the drive shaft slidably held within the

outer tube by balls, Fig. 13. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Belef/Ross with the teachings of Nash for providing a drive assembly comprising two tubes in sliding arrangement held in place by ball bearings.

Further, Belef/Ross does not directly disclose the console unit being connectable to an infusion source and the console unit controls the level of infusion. Nash, in the analogous art, teaches a controllable infusion source C10 L14-18. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Belef/Ross with the infusion source as taught by Nash for further clearing a vessel lumen.

8. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belef in view of Ross further in view of Wulfman et al. (US 5,584,843) (“Wulfman”).

The combination of Befef/Ross teaches the invention as substantially claimed (see above). However, this combination does not directly disclose a guidewire brake and control system. Wulfman, in the analogous art, teaches a guidewire brake C5 L17-20. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Belef/Ross with the guidewire brake as taught by Wulfman for a system in which the guidewire does not need to be manipulated during or between cutting actions.

9. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belef in view of Ross further in view of Ritchart et al. (US 5,769,086) (“Ritchart”).

The combination of Befef/Ross teaches the invention as substantially claimed (see above). However, this combination does not directly disclose an automated operating condition based on at least one input parameter. Ritchart, in the analogous art, teaches an automated control system that operates after input from a user, see abstract and claim 12. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Belef/Ross with the automated operation as taught by Ritchart for generating repeatable results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEANNA K. HALL whose telephone number is (571)272-2819. The examiner can normally be reached on M-F 9:00am-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deanna K. Hall/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767

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